



Clinical trial results:

A long-term follow-up study to assess bone mineral density in subjects with uterine fibroids completing the Phase 3 studies of linzagolix, PRIMROSE 1 or PRIMROSE 2

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2021-000452-19 |
| Trial protocol | HU PL LV BG RO |
| Global end of trial date | 14 November 2022 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 18 November 2023 |
| First version publication date | 18 November 2023 |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | 20-OBE2109-007 |
|-----------------------|----------------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Kissei Pharmaceutical Co., Ltd. |
| Sponsor organisation address | 3-1-3 Koishikawa, Bunkyo-ku, Tokyo, Japan, 112-0002 |
| Public contact | Kissei Pharmaceutical Co., Ltd., Clinical Projects Management, rinsyousiken@pharm.kissei.co.jp |
| Scientific contact | Kissei Pharmaceutical Co., Ltd., Clinical Projects Management, rinsyousiken@pharm.kissei.co.jp |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 14 November 2022 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 14 November 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to describe BMD changes for up to 24 months following previous treatment with placebo or linzagolix at 100 mg or 200 mg alone or with ABT for at least 20 weeks in the context of the PRIMROSE 1 and PRIMROSE 2 studies.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki (adopted Version Fortaleza, Brazil October 2013) as well as with the valid national law(s) of the participating countries, with the International Conference on Harmonisation (ICH) Harmonised Tripartite Guideline for GCP, the US Code of Federal Regulations or the EU Clinical Trial Directive and applicable local laws and regulations.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 15 April 2021 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Poland: 27 |
| Country: Number of subjects enrolled | Romania: 4 |
| Country: Number of subjects enrolled | Bulgaria: 4 |
| Country: Number of subjects enrolled | Czechia: 5 |
| Country: Number of subjects enrolled | Hungary: 7 |
| Country: Number of subjects enrolled | Latvia: 1 |
| Country: Number of subjects enrolled | Ukraine: 11 |
| Country: Number of subjects enrolled | United States: 75 |
| Worldwide total number of subjects | 134 |
| EEA total number of subjects | 48 |

Notes:

Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |

| | |
|--|-----|
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 134 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The trial was conducted in 3 sites in Bulgaria, 4 sites in Czech Republic, 4 sites in Hungary, 1 site in Latvia, 6 sites in Poland, 1 site in Romania, 5 sites in Ukraine and 32 sites in the US.

Pre-assignment

Screening details:

Of the 137 screened subjects, 134 were enrolled, and 130 were included in SS. Although this study consists of 7 arms, the values of "LGX 200 mg + AB Placebo" group is not included in the below tables because it consists of only 1 subject. Therefore, the No. of "Started" subjects of Period 1 are equal to neither the No. of SS nor enrolled subjects.

Period 1

| | |
|------------------------------|--|
| Period 1 title | For BMD and Safety Evaluation (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | LGX Placebo + AB Placebo |

Arm description:

Linzagolix Placebo + Add-back Placebo for 52 weeks

| | |
|--|--------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Linzagolix placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Linzagolix: 0 mg

| | |
|--|-----------------|
| Investigational medicinal product name | E2/NETA placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

ESTRADIOL HEMIHYDRATE: 0 mg
NORETHISTERONE ACETATE: 0 mg

| | |
|------------------|--|
| Arm title | LGX Placebo + AB Placebo / LGX 200 mg + AB |
|------------------|--|

Arm description:

Linzagolix Placebo + Add-back Placebo for 24 weeks, then Linzagolix 200 mg + Add-back for 28 weeks

| | |
|--|--------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Linzagolix placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Linzagolix: 0 mg

| | |
|---|-------------------------|
| Investigational medicinal product name | E2/NETA placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: ESTRADIOL HEMIHYDRATE: 0 mg NORETHISTERONE ACETATE: 0 mg | |
| Investigational medicinal product name | Linzagolix |
| Investigational medicinal product code | |
| Other name | OBE2109 |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details: Linzagolix: 100 mg X 2 | |
| Investigational medicinal product name | E2/NETA |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: ESTRADIOL HEMIHYDRATE: 1 mg NORETHISTERONE ACETATE: 0.5 mg | |
| Arm title | LGX 100 mg + AB Placebo |
| Arm description: Linzagolix 100 mg + Add-back Placebo for 52 weeks | |
| Arm type | Experimental |
| Investigational medicinal product name | Linzagolix |
| Investigational medicinal product code | |
| Other name | OBE2109 |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details: Linzagolix: 100 mg | |
| Investigational medicinal product name | E2/NETA placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: ESTRADIOL HEMIHYDRATE: 0 mg NORETHISTERONE ACETATE: 0 mg | |
| Arm title | LGX 100 mg + AB |
| Arm description: Linzagolix 100 mg + Add-back for 52 weeks | |
| Arm type | Experimental |
| Investigational medicinal product name | Linzagolix |
| Investigational medicinal product code | |
| Other name | OBE2109 |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

| | |
|---|---|
| Dosage and administration details: | |
| Linzagolix: 100 mg | |
| Investigational medicinal product name | E2/NETA |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| ESTRADIOL HEMIHYDRATE: 1 mg | |
| NORETHISTERONE ACETATE: 0.5 mg | |
| Arm title | LGX 200 mg + AB Placebo / LGX 200 mg + AB |
| Arm description: | |
| Linzagolix 200 mg + Add-back Placebo for 24 weeks, then Linzagolix 200 mg + Add-back for 28 weeks | |
| Arm type | Experimental |
| Investigational medicinal product name | Linzagolix |
| Investigational medicinal product code | |
| Other name | OBE2109 |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Linzagolix: 100 mg X 2 | |
| Investigational medicinal product name | E2/NETA placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| ESTRADIOL HEMIHYDRATE: 0 mg | |
| NORETHISTERONR ACETATE: 0 mg | |
| Investigational medicinal product name | E2/NETA |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| ESTRADIOL HEMIHYDRATE: 1 mg | |
| NORETHISTERONE ACETATE: 0.5 mg | |
| Arm title | LGX 200 mg + AB |
| Arm description: | |
| Linzagolix 200 mg + add-back for 52 weeks | |
| Arm type | Experimental |
| Investigational medicinal product name | Linzagolix |
| Investigational medicinal product code | |
| Other name | OBE2109 |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Linzagolix: 100 mg X 2 | |
| Investigational medicinal product name | E2/NETA |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |

| | |
|--------------------------|----------|
| Routes of administration | Oral use |
|--------------------------|----------|

Dosage and administration details:

ESTRADIOL HEMIHYDRATE: 1 mg

NORETHISTERONE ACETATE: 0.5 mg

| Number of subjects in period 1 ^[1] | LGX Placebo + AB Placebo | LGX Placebo + AB Placebo / LGX 200 mg + AB | LGX 100 mg + AB Placebo |
|---|--------------------------|--|-------------------------|
| | | | |
| Started | 7 | 26 | 22 |
| Completed | 7 | 23 | 16 |
| Not completed | 0 | 3 | 6 |
| Consent withdrawn by subject | - | - | 2 |
| Special military situation in Ukraine | - | 3 | 1 |
| Lost to follow-up | - | - | 2 |
| Facility closed | - | - | 1 |

| Number of subjects in period 1 ^[1] | LGX 100 mg + AB | LGX 200 mg + AB Placebo / LGX 200 mg + AB | LGX 200 mg + AB |
|---|-----------------|---|-----------------|
| | | | |
| Started | 23 | 30 | 21 |
| Completed | 21 | 23 | 19 |
| Not completed | 2 | 7 | 2 |
| Consent withdrawn by subject | 2 | 3 | 1 |
| Special military situation in Ukraine | - | 1 | 1 |
| Lost to follow-up | - | 2 | - |
| Facility closed | - | 1 | - |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: A total of 134 subjects were enrolled in the study and 130 subjects were used in BMD and Safety evaluation, and the remaining four subjects were excluded because no DXA data were obtained during the study.

Moreover, because the LGX 200mg group was excluded from reporting group, one subject of this group is not presented in the below tables.

Baseline characteristics

Reporting groups

| | |
|--|--|
| Reporting group title | LGX Placebo + AB Placebo |
| Reporting group description: Linzagolix Placebo + Add-back Placebo for 52 weeks | |
| Reporting group title | LGX Placebo + AB Placebo / LGX 200 mg + AB |
| Reporting group description: Linzagolix Placebo + Add-back Placebo for 24 weeks, then Linzagolix 200 mg + Add-back for 28 weeks | |
| Reporting group title | LGX 100 mg + AB Placebo |
| Reporting group description: Linzagolix 100 mg + Add-back Placebo for 52 weeks | |
| Reporting group title | LGX 100 mg + AB |
| Reporting group description: Linzagolix 100 mg + Add-back for 52 weeks | |
| Reporting group title | LGX 200 mg + AB Placebo / LGX 200 mg + AB |
| Reporting group description: Linzagolix 200 mg + Add-back Placebo for 24 weeks, then Linzagolix 200 mg + Add-back for 28 weeks | |
| Reporting group title | LGX 200 mg + AB |
| Reporting group description: Linzagolix 200 mg + add-back for 52 weeks | |

| Reporting group values | LGX Placebo + AB Placebo | LGX Placebo + AB Placebo / LGX 200 mg + AB | LGX 100 mg + AB Placebo |
|--|--------------------------|--|-------------------------|
| Number of subjects | 7 | 26 | 22 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 7 | 26 | 22 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | 39.9 | 42.2 | 43.9 |
| standard deviation | ± 9.0 | ± 6.3 | ± 4.2 |
| Gender categorical Units: Subjects | | | |
| Female | 7 | 26 | 22 |
| Male | 0 | 0 | 0 |

| | | | |
|------------------------|-----------------|---|-----------------|
| Reporting group values | LGX 100 mg + AB | LGX 200 mg + AB Placebo / LGX 200 mg + AB | LGX 200 mg + AB |
|------------------------|-----------------|---|-----------------|

| | | | |
|---|-------|-------|-------|
| Number of subjects | 23 | 30 | 21 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 23 | 30 | 21 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 43.0 | 41.6 | 44.7 |
| standard deviation | ± 5.4 | ± 5.7 | ± 5.0 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 23 | 30 | 21 |
| Male | 0 | 0 | 0 |

| | | | |
|---|-------|--|--|
| Reporting group values | Total | | |
| Number of subjects | 129 | | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 0 | | |
| Children (2-11 years) | 0 | | |
| Adolescents (12-17 years) | 0 | | |
| Adults (18-64 years) | 129 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 129 | | |
| Male | 0 | | |

End points

End points reporting groups

| | |
|--|--|
| Reporting group title | LGX Placebo + AB Placebo |
| Reporting group description: | |
| Linzagolix Placebo + Add-back Placebo for 52 weeks | |
| Reporting group title | LGX Placebo + AB Placebo / LGX 200 mg + AB |
| Reporting group description: | |
| Linzagolix Placebo + Add-back Placebo for 24 weeks, then Linzagolix 200 mg + Add-back for 28 weeks | |
| Reporting group title | LGX 100 mg + AB Placebo |
| Reporting group description: | |
| Linzagolix 100 mg + Add-back Placebo for 52 weeks | |
| Reporting group title | LGX 100 mg + AB |
| Reporting group description: | |
| Linzagolix 100 mg + Add-back for 52 weeks | |
| Reporting group title | LGX 200 mg + AB Placebo / LGX 200 mg + AB |
| Reporting group description: | |
| Linzagolix 200 mg + Add-back Placebo for 24 weeks, then Linzagolix 200 mg + Add-back for 28 weeks | |
| Reporting group title | LGX 200 mg + AB |
| Reporting group description: | |
| Linzagolix 200 mg + add-back for 52 weeks | |

Primary: Change in Lumbar Spine BMD at 24 Months from Post-treatment Baselinee

| | |
|------------------------|--|
| End point title | Change in Lumbar Spine BMD at 24 Months from Post-treatment Baselinee ^[1] |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| 24 months | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point.

| End point values | LGX Placebo + AB Placebo | LGX Placebo + AB Placebo / LGX 200 mg + AB | LGX 100 mg + AB Placebo | LGX 100 mg + AB |
|--------------------------------------|--------------------------|--|-------------------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 20 | 15 | 17 |
| Units: g/cm ² | | | | |
| arithmetic mean (standard deviation) | 0.120 (± 1.848) | -0.375 (± 4.187) | 1.477 (± 5.935) | 1.507 (± 6.771) |

| | | | | |
|------------------|--|-----------------|--|--|
| End point values | LGX 200 mg + AB Placebo / LGX 200 mg + | LGX 200 mg + AB | | |
|------------------|--|-----------------|--|--|

| | | | | |
|--------------------------------------|-----------------|------------------|--|--|
| | AB | | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 21 | 18 | | |
| Units: g/cm ² | | | | |
| arithmetic mean (standard deviation) | 3.173 (± 5.885) | -0.319 (± 4.083) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Change in Femoral Neck BMD at 24 Months from Post-treatment Baseline

| | |
|-----------------|---|
| End point title | Change in Femoral Neck BMD at 24 Months from Post-treatment Baseline ^[2] |
|-----------------|---|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

24 months

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point.

| End point values | LGX Placebo + AB Placebo | LGX Placebo + AB Placebo / LGX 200 mg + AB | LGX 100 mg + AB Placebo | LGX 100 mg + AB |
|--------------------------------------|--------------------------|--|-------------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 21 | 15 | 17 |
| Units: g/cm ² | | | | |
| arithmetic mean (standard deviation) | 3.230 (± 7.789) | -2.071 (± 10.565) | 1.236 (± 6.635) | -0.113 (± 5.861) |

| End point values | LGX 200 mg + AB Placebo / LGX 200 mg + AB | LGX 200 mg + AB | | |
|--------------------------------------|---|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 18 | | |
| Units: g/cm ² | | | | |
| arithmetic mean (standard deviation) | 1.643 (± 4.749) | -1.259 (± 3.352) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Change in Total Hip BMD at 24 Months from Post-treatment Baseline

| | |
|-----------------|--|
| End point title | Change in Total Hip BMD at 24 Months from Post-treatment Baseline ^[3] |
|-----------------|--|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

24 months

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point.

| End point values | LGX Placebo + AB Placebo | LGX Placebo + AB Placebo / LGX 200 mg + AB | LGX 100 mg + AB Placebo | LGX 100 mg + AB |
|--------------------------------------|--------------------------|--|-------------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 21 | 15 | 17 |
| Units: g/cm ² | | | | |
| arithmetic mean (standard deviation) | 5.263 (± 5.548) | -2.633 (± 9.196) | 0.431 (± 3.337) | -0.377 (± 3.842) |

| End point values | LGX 200 mg + AB Placebo / LGX 200 mg + AB | LGX 200 mg + AB | | |
|--------------------------------------|---|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 18 | | |
| Units: g/cm ² | | | | |
| arithmetic mean (standard deviation) | 1.559 (± 4.431) | 0.697 (± 4.951) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Up to 24 months

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 23.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------------------|
| Reporting group title | LGX Placebo + AB Placebo |
|-----------------------|--------------------------|

Reporting group description: -

| | |
|-----------------------|--|
| Reporting group title | LGX Placebo + AB Placebo / LGX 200 mg + AB |
|-----------------------|--|

Reporting group description: -

| | |
|-----------------------|-------------------------|
| Reporting group title | LGX 100 mg + AB Placebo |
|-----------------------|-------------------------|

Reporting group description: -

| | |
|-----------------------|-----------------|
| Reporting group title | LGX 100 mg + AB |
|-----------------------|-----------------|

Reporting group description: -

| | |
|-----------------------|---|
| Reporting group title | LGX 200 mg + AB Placebo / LGX 200 mg + AB |
|-----------------------|---|

Reporting group description: -

| | |
|-----------------------|-----------------|
| Reporting group title | LGX 200 mg + AB |
|-----------------------|-----------------|

Reporting group description: -

| Serious adverse events | LGX Placebo + AB Placebo | LGX Placebo + AB Placebo / LGX 200 mg + AB | LGX 100 mg + AB Placebo |
|---|--------------------------|--|-------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 26 (0.00%) | 0 / 22 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| Serious adverse events | LGX 100 mg + AB | LGX 200 mg + AB Placebo / LGX 200 mg + AB | LGX 200 mg + AB |
|---|-----------------|---|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 23 (0.00%) | 0 / 30 (0.00%) | 0 / 21 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | LGX Placebo + AB Placebo | LGX Placebo + AB Placebo / LGX 200 mg + AB | LGX 100 mg + AB Placebo |
|---|-----------------------------|--|----------------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 0 / 7 (0.00%) | 0 / 26 (0.00%) | 0 / 22 (0.00%) |

| Non-serious adverse events | LGX 100 mg + AB | LGX 200 mg + AB Placebo / LGX 200 mg + AB | LGX 200 mg + AB |
|---|-----------------|---|-----------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 0 / 23 (0.00%) | 0 / 30 (0.00%) | 0 / 21 (0.00%) |

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: This is a long-term follow-up study, and no procedure-related AE during the study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported